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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,246	12/11/2006	Takashi Okada	OKAD3006/GAD	6540

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EXAMINER	
SCHULTZ, JAMES	
ART UNIT	**PAPER NUMBER**
1633	

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03/17/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/554,246	OKADA ET AL.	
	Examiner	Art Unit	
	JD SCHULTZ	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *January 8, 2010, and August 24, 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-39* is/are pending in the application.

4a) Of the above claim(s) *27-32 and 39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-26 and 33-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's responses filed January 8, 2010, and August 24, 2009 have been considered. Rejections and/or objections not reiterated from the previous office action mailed April 22, 2009 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Since all previous claims were canceled by applicants in their most recent amendments, the instant rejections set forth below are new and necessitated by applicant's amendments. Accordingly, the instant action is made FINAL.

Election/Restrictions

Applicant's election without traverse of the species "in vivo", and the disease "amyotrophic lateral sclerosis" (ALS) in the reply filed on January 8, 2010 is acknowledged.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 27-32, 37 and 39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected species (i.e. tumor cells), there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on January 8, 2010.

A complete reply to the final rejection must include cancellation of nonelected subject matter or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20, 22, 24, 27, 29, 30, 36, and 37 rejected under 35 U.S.C. 102(b) as being clearly anticipated by Townes (WO/97/47307).

The claimed invention is drawn to a method for increasing gene transfer efficiency associated with the use of adeno-associated viral vectors, comprising administering an effective dose of a histone deacetylase inhibitor to a subject in need thereof so that an episomal AAV genome, which has not undergone chromosomal integration, undergoes histone modification to enhance gene expression of the episomal AAV genome. The claimed invention further defines the timing of the administration of the deacetylase inhibitor to be simultaneous with, or immediately before or after administration of the AAV vector.

Townes et al. teach a method for increasing gene transfer efficiency associated with the use of adeno-associated viral vectors, comprising administering an effective dose of a histone deacetylase inhibitor to a subject in need thereof so that an episomal AAV genome (see page 2 of Townes), which has not undergone chromosomal integration, undergoes histone modification to enhance gene expression of the episomal AAV genome. Townes et al. also teach that the timing

of the administration of the deacetylase inhibitor to be simultaneous with, or after administration of the AAV vector (see page 6).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 20-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Townes et al. as applied to claim20, 22, 24, 27, 29, 30, 36, and 37 above, and further in view of Nakajima et al. (EXPERIMENTAL CELL RESEARCH 241, 126–133 (1998)), and Alisky et al. (HUMAN GENE THERAPY 11:2315–2329 (November 20, 2000).

The invention is described above, and further comprises the use of the specific HDAC inhibitor FR901228, and that the cells in which the method is practiced are derived from a subject who has ALS.

Townes et al. et al. is relied upon as above. Townes teaches the use multiple HDAC-specific inhibitors, including at least five forms of butyrate, trichostatin A and trapoxin. Townes does not teach the use of the specific HDAC inhibitor FK228, or that cells from subjects having ALS should be used.

Nakajima et al. teach that FR901228 (i.e. compound I as claimed in is at least claim 21) is a potent inhibitor of histone deacetylase and is identical in function to both trichostatin and trapoxin.

Alisky et al. teaches the use of AAV vectors in delivering genes to cells from subjects having ALS.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the histone deacetylase inhibitor FR 901228 in place of the histone deacetylase inhibitors butyrate, trichostatin, and trapoxin of Townes et al., since Nakajima et al. teach that 901228 is a potent inhibitor of histone deacetylase and is identical in function to both trichostatin and trapoxin. It is prima facie obvious to substitute equivalents known in the art to be useful for the same purpose. Furthermore, it would have been obvious to use cells from a subject having ALS since the use of gene therapy in treating ALS had been previously taught by Alisky et al. Because all compounds and steps were known in the art, one of ordinary skill would have had a reasonable expectation in practicing the claimed invention.

Applicant's arguments with respect to all previously set forth rejections have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JD SCHULTZ whose telephone number is (571)272-0763. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JD SCHULTZ/
Primary Examiner, Art Unit 1633